UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION MDL 2570,	)	No. 1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to All Actions	)	

DISCOVERY ORDER

On April 27, 2016, the Court held a telephonic status conference and heard argument on Defendant Cook Medical's motion for protective order. [Filing No. 1329.] By way of this motion, Cook seeks to bar Plaintiffs from seeking discovery concerning Cook's alleged failure to report adverse events associated with its IVC filters to the United States Food and Drug Administration.

Cook's motion is premised in part on the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001), that state law fraud-on-the-FDA claims conflict with, and therefore are impliedly preempted by, the Federal Food, Drug, and Cosmetics Act. The FDCA gives the FDA sole authority to enforce compliance with the FDCA's disclosure and other provisions. Thus, Cook argues that since Plaintiffs cannot enforce compliance, Cook's report submissions to the FDA are irrelevant and inadmissible.

In support of its argument, Cook cites to *In re Incretin Mimetics Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 142227 (S.D. Cal. Oct. 6, 2014). In *Incretin*, plaintiffs sought to compel production of documents discussing adverse event reports to determine whether defendant misrepresented or under-reported information to the FDA in connection with its drug at issue.

Id. at 187-88. Relying in part on *Buckman*, the *Incretin* court denied plaintiffs' motion to compel. *Id.* at 201. Cook asks this Court for a similar ruling.

For three reasons, the holdings of *Buckman* and *Incretin* are not particularly helpful to Cook's position. First, unlike *Buckman* and *Incretin*, Plaintiffs here are not asserting fraud-on-the-FDA claims, and thus preemption is not in play. Plaintiffs simply want to discover the reports Cook made to the FDA. Second, while the *Incretin* court's holding was premised on a finding that production of source documents and databases would be unduly burdensome, *Id.* at 200, Cook makes only a one-sentence reference to burden and expense. [Filing No. 1329, at ECF p. 5.] As the party moving for a protective order, the burden is on Cook to establish facts supporting undue burden. *Nives v. OPA, Inc.*, 948 F. Supp. 2d 887, 891 (N.D. Ill. 2013). Cook's passing reference to expense comes nowhere close to establishing undue burden.[1] Third, whereas the *Incretin* defendant denied misrepresenting or under-reporting information to the FDA, this is not exactly the situation in the case at hand. As Plaintiffs point out, discovery revealed that Cook only reported device complaints to the FDA (and therefore to MAUDE[2]) for filters marketed in the United States and withheld complaints for the same products marketed outside the country. [Filing No. 1367, at ECF p. 3.] Cook does not dispute this, though it does dispute that such reporting constitutes an irregularity. As far as the Court can discern, Cook does

[1] Cook also claims discovery of its reporting to the FDA is not proportional to the needs of the case. [Filing No. 1329, ECF at p. 5.] The Court appreciates due regard for proportionality, consistent with the recently revised Fed. R. Civ. P. 26(b)(1) (discovery must be "proportional to the needs of the case" considering the factors set forth in the revised rule). However, again Cook does not develop this argument, and in any event proportionality in this high-stakes, costly MDL would necessarily be construed broadly. Thus, the only issue Cook develops in its motion for protective order is whether the discovery is relevant to any claim or defense in the case.

[2] The MAUDE database is the FDA's Manufacturer and User Facility Device Experience database that houses the medical device reports of suspected device-associated deaths, serious injuries, and malfunctions.

not deny under-reporting information to the FDA like the defendant in *Incretin*. Thus, *Buckman* and *Incretin* do not provide a solid foundation for Cook's requested protective order.

Cook's reliance on *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312 (S.D. Fla. 2010), does not fare much better. The *Trasylol* court precluded plaintiffs from offering evidence at trial about whether Bayer provided inadequate information to the FDA in connection with the marketing and sale of a prescription drug. *Id.* at 1131. Though *Trasylol* contains a comprehensive discussion of *Buckman* and numerous other cases, the problem for Cook is that *Trasylol* involved a motion *in limine*. The *Trasylol* decision does not stand for the proposition that such evidence is not discoverable. Rather, apparently following discovery of such evidence, the judge concluded that it was not admissible at trial. *Id*. While Cook will undoubtedly raise similar arguments in this case, they are appropriately presented at a later stage in this litigation. The discovery sought by Plaintiffs is not so far afield that the Court can say with certainty at this juncture it will not be admissible at trial. Accordingly, *Trasylol* does not convince the Court to preclude this discovery.

More on point is the recent case of *In re Bard IVC Filters Products Liability Litigation*, MDL 15-02641-PHX DGC (D. Ariz. April 1, 2016), which addresses the issue of discoverability. Specifically, the *Bard* court stated:

> The Court views discovery relating to under-reporting or non-reporting of problems with retrievable filters to be clearly relevant to this case. Actual failure rates will be relevant to Plaintiffs' negligence and product defect claims. Evidence regarding representations made by Defendants concerning failure rates will be relevant to Plaintiffs' claims for fraud and misrepresentation.

Id. at 3.

This Court agrees with the analysis in *Bard*. Plaintiffs allege that Cook knowingly presents false information regarding the safety profile of its filters to physicians and the public,

and uses this false information as a promotional tool and in the labeling of its IVC products. Similar to *Bard*, Cook's actual reports to the FDA are relevant to Plaintiffs' claims and examination of potential liability. Cook's reports to the FDA are particularly relevant to analyze the learned intermediary defense because they are what an intermediary would have relied on. Cook's argument of limited relevancy is not enough to overcome the broad standard of relevance applicable in discovery. Fed. R. Civ. P. 26(b)(1); *see Bank of Am., N.A. v. Wells Fargo Bank, N.A.*, No. 12 C 9612, 2014 WL 3639190, at *3 (N.D. Ill. July 23, 2014) ("Relevance in discovery is broader than relevance at trial; during discovery, a broad range of potentially useful information should be allowed when it pertains to issues raised by the parties' claims."). As a result, the disputed information is at least discoverable.

Cook tries to distinguish *Bard* on the basis that the defendant in that case had received an FDA warning letter, whereas Cook has not. This strikes the Court as the proverbial distinction without a difference. Warning letter or not, case law supports a finding that this information is relevant and discoverable. Cook's motion for a protective order [Filing No. 1329] is denied.

Date: 5/12/2016

Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

Distribution to all electronically registered counsel of record via CM/ECF.
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